JUN 3 0 2004

Elcam Medical

510(k) Summary

1. **Company Name –**
Elcam Medical ACAL
Kibbutz BarAm
Merom Hagalil 13860
Israel

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Submitter and
Contact Name: Tali Hazan
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General Manager
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Date prepared: June 8, 2004

2. **Device Name –**
Proprietary name: None
Common / Usual Name: H-Flow Valve
Trade Name: H-Flow Valve

K034043

The device has been classified in Class II under the following classification:

Classification name	Product Code	Regulation No.	Panel Identification
Catheter, Intravascular, Diagnostic	DQO	870.1200	Cardiovascular Devices Panel

3. **Predicate Device –**
Floswitch® HP, Boston Scientific Corp. 2710 Orchard Pkwy. , San Jose, CA 95113, cleared under 510(k) no. K913871.

4. **Description of the Device –**
The H-Flow Valve developed by Elcam Medical ACAL can be connected, by a standard male luer-lock, to any standard Angiographic catheter. The device has a septum that prevents blood loss when nothing is connected to the female port of the device. Common guide-wires (in diameter of 0.014" to 0.038") can be introduced via the device (through the slit septum) without the need to open the valve and without bleeding due to the intra-catheter human arterial pressure. When connecting a standard male luer to the device's female port (for injection of contrast media or flushing with saline), the septum opens (with the aid of the actuator) to allow fluid flow.
An accessory called 'Stylet' is added to the device and has two purposes: **a)** to make sure the slit is open prior to initial use. **b)** To aid with insertion of small and angled guide wires.

5. **Indications for Use –**
The device is an Angiographic accessory intended for use as self-sealing Hemostatic luer activated valve for angiography and other high-pressure applications.

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6. **Substantial Equivalence** –
The H-Flow Valve has the same intended use as the Floswitch® HP, cleared under 510(k) no. K913871 and has equivalent performance characteristics. Both products are valves activated; the H-Flow Valve is activated by connection to the male luer while the Floswitch® HP is activated by an on/off switch.
All other technological characteristics are similar and the functional performance tests performed on both devices show equivalent performance capabilities.
The evaluation of the H-Flow Valve does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate device.

7. **Performance Testing** –
Performance tests related to functionality and biocompatibility of both new and predicate device were performed. Tests results showed that the product met all established acceptance criteria and therefore has equivalent performances capabilities and properties.

8. **Conclusion** –
The evaluation of the H-Flow Valve does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

ELCAM Medical ACAL
c/o Mr. Tali Hazan
Kibbutz BarAm
M.P. Merom HaGalil 13860
Israel

Re: K034043
Trade/Device Name: H-Flow Valve
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: DQO
Dated: June 9, 2004
Received: June 15, 2004

Dear Mr. Hazan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K034043

Device Name: H-Flow Valve

Indications for Use: The device is an Angiographic accessory intended for use as self-sealing Hemostatic luer activated valve for angiography and other high-pressure applications.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE):

Donna R. Vochmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K034043